

REMARKS

In the present Amendment, claims 1, 3, 9 and 11 have been amended to improve their form. No new matter has been added, and entry of the Amendment is respectfully requested.

Claims 1-13 are pending, of which claims 9-12 are withdrawn from consideration.

Independent claim 9 has been amended to include all of the limitations of amended product claim 1. If claim 1 is found to be allowable, Applicants respectfully request rejoinder of withdrawn method claims 9-12 pursuant to MPEP §821.04(b).

At page 2 of the Office Action, the Office rejects claims 1-8 and 13 under 35 U.S.C. § 101, because these claims read on the organism which is found in nature, and thus is unpatentable to Applicant.

In this respect, the Examiner suggests that Applicants use the language “a biologically pure culture” in connection with the strain to identify a product that is not found in nature.

Without acquiescing in the merits of the rejection and solely to advance prosecution, claim 1 has been amended to recite that the *Lactococcus* is “a biologically pure culture.” In addition, claims 3 and 11 have been amended to recite “*garvieae*.”

In view of the above, reconsideration and withdrawal of the §101 rejection of claims 1-8 and 13 are respectfully requested.

At page 2 of the Office Action, the Office rejects claims 3 and 13 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

In this respect, the Examiner asserts that for compliance with the rules, Applicants must file a Statement of Availability averring that the deposited material that is recited in the claims has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure and that all restrictions on the

availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

The strain defined in claims 3 and 13 has been deposited under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. A copy of the official Receipt, and an English translation thereof are attached. Also, submitted herewith is the required Statement of Availability.

Accordingly, reconsideration and withdrawal of the §112 rejection of claims 3 and 13 are respectfully requested.

At page 4 of the Office Action, the Office rejects claims 1 and 3-8 under 35 U.S.C. § 102(e) as allegedly being anticipated by Setchell *et al.* (U.S. Patent No. 7,396,855, hereinafter Setchell).

Applicants submit that this rejection should be withdrawn because Setchell does not disclose or render obvious the present invention.

The Examiner asserts that Setchell discloses a composition comprising an equol-producing strain of *Lactococcus*, as an essential component, which further contains soy milk, daidzein and equol. In this respect, the Examiner asserts that the claimed composition neither recites the amount of equol nor the amount of *Lactococcus* present, and thus the invention is allegedly anticipated by Setchell.

Applicants respectfully disagree.

Setchell discloses a mixed culture of microorganisms that convert daidzein to equol. Specifically, Setchell discloses that when samples of a daidzein-enriched soy milk were inoculated with a *mixed culture* containing: *B. lactis*, *L. acidophilus*, *L. lactis*, *E. faecium*, *L. casei* and *L. salivarius*, daidzein loss (i.e., conversion of daidzein to equol) to approximately

50% of the initial level occurred in up to 25 hours. *See* Setchell, column 25 and 26, and Example 5.

That is, Setchell discloses that the transformation of daidzein to equol can be observed when six strains, i.e., *B. lactis*, *L. acidophilus*, *L. lactis*, *E. faecium*, *L. casei* and *L. salivarius*, are used in a combined manner.

However, Setchell nowhere discloses that daidzein can be converted into equol using these six strains singly.

Usually, the production of equol from daidzein follows the synthetic route of daidzein → dihydrodaidzein → tetrahydrodaidzein → equol. Therefore, in order to produce equol using a single strain, the strain must have all the enzymes needed for these conversions.

However, Setchell merely teaches that the conversion of daidzein to equol was observed when a mixed culture containing the six strains was used. In other words, Setchell is silent about the production of equol using a single strain that can carry out all of the conversions of daidzein → dihydrodaidzein → tetrahydrodaidzein → equol.

In contrast, the instant claims recite a novel strain of lactic acid bacterium which can be used *alone* to utilize daidzein compounds in the soy milk to make equol. In this respect, the specification discloses that no lactic acid bacteria of the genus *Lactococcus* are known that have an equol producing ability (i.e., that can make equol from daidzein compounds in soy milk). *See* Specification, page 10, lines 12-16.

Thus, the recitation of the composition comprising a biologically pure culture of *Lactococcus* which has an equol producing ability, as recited in amended claim 1, distinguishes the instant claims from the disclosure in Setchell (i.e., a mixed culture of microorganisms that convert daidzein to equol). Further, claim 1 has been amended to *clearly specify* that the

bacterial strain belonging to the genus *Lactococcus*, rather than other components of the claimed composition, has an equol producing ability

Accordingly, Setchell fails to teach each and every element of the claimed invention, and thus does not anticipate the claimed invention.

In view of the above, reconsideration and withdrawal of the §102(e) rejection based on Setchell are respectfully requested.

At page 5 of the Office Action, the Office rejects claims 1-8 and 13 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Setchell in view of Elliott *et al.* (Journal of Clinical Microbiology, 1991, 29(12): 2731-2734, hereinafter Elliott).

Applicants submit that this rejection should be withdrawn because Setchell and Elliott do not disclose or render obvious the present invention, either alone or in combination.

The Examiner admits that Setchell does not disclose *L. garvieae* but rather *L. lactis*. In an attempt to rectify this deficiency of Setchell the Examiner cites Elliott. In this respect, the Examiner asserts that Elliott demonstrates that the classification boundaries between *L. lactis* and *L. garvieae* are not clearly defined.

With regard to the specific strain included in the claimed composition, the Examiner alleges that even if the claimed microorganism is not identical to the referenced microorganism, the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism, such as belonging to the same genus *Lactococcus* and producing equol. Accordingly, the Examiner concludes that the claimed invention as a whole was *prima facie* obvious at the time the claimed invention was made.

Applicants respectfully disagree.

As discussed above with respect to the § 102(e) rejection based on Setchell, Setchell fails to teach or suggest a biologically pure culture of lactic acid bacterial strain belonging to the genus *Lactococcus* which has an equal producing ability, as recited in amended claim 1. Further, Setchell fails to teach or suggest a lactic acid bacterial strain belonging to the genus *Lactococcus* as deposited under FERM BP-10036, as recited in claims 3 and 13. Elliott does not cure the deficiencies of Setchell.

Accordingly, Setchell alone or in combination with Elliott fails to teach or suggest each and every element of the claimed invention, and thus cannot render Applicants' claimed invention obvious.

In view of the above, reconsideration and withdrawal of the §103(a) rejection based on Setchell in view of Elliott are respectfully requested.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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